IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., Inc. Plaintiff, v. RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Defendant.	C.A. No. 07-229 (GMS)
RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Counterclaim Plaintiff, v. MERCK & CO., Inc. Counterclaim Defendant.	

ANSWERING BRIEF ON CLAIM CONSTRUCTION OF DEFENDANTS
RANBAXY INC. AND RANBAXY LABORATORIES LIMITED

OF COUNSEL:
Mark Boland
Kenneth Burchfiel
Michael Dzwonczyk
Chid Iyer
Renita Rathinam
Sughrue Mion PLLC
2100 Pennsylvania Ave., N.W.
Suite 800
Washington, D.C. 20037
(202) 293-7060

Dated: December 21, 2007

Frederick L. Cottrell III (#2555)
Cottrell @rlf.com
Kelly E. Farnan (#4395)
Farnan@rlf.com
Richards, Layton & Finger
One Rodney Square
920 N. King Street
Wilmington, DE 19899
(302) 651-7700
Attorneys for Defendant/Counterclaimant Ranbaxy Laboratories Limited and Ranbaxy Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes and Regulations

Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy") submit the present answering brief in response to Merck's proposed claim construction.

I. Merck's misstatements of fact

Merck misstates the facts with respect to the claimed subject matter, and the compound cilastatin, in its statement of background facts.[1] The "genus" has no requirement that R^3 contains 2 to 15 carbon atoms. (Br. 3).[2] This is an argument, not a fact. The fact is that Claim 1 literally recites that R^3 is an alkyl group that may contain 1 to 15 carbon atoms; indeed, this is the only definition of the "genus" provided in the '868 patent specification. (1:60-61, A2). Merck's statement of "facts" does not address or even acknowledge this express definition of R^3.

Merck incorrectly states that the compound illustrated at page 3 of its brief is cilastatin. The structure of cilastatin is described in Merck's package insert, which clearly indicates that cilastatin is an isomer having a specific (R) conformation in the 7-[(R)-2-amino-2-carboxyethyl]thio substituent , and an (S) conformation in the 2-(2,2-dimethylcyclopropane-carboxamido) group. (A2496). That specific stereo-conformation is not present in the formula on which Merck now relies, and Merck omits any mention of the three-dimensional structure of cilastatin.

As correctly stated in Ranbaxy's opening brief, no claim of the '868 patent is specific to the compound known as cilastatin. Contrary to Merck's statement (Br. 4), Claims 19 and 20 are not specifically directed to cilastatin, because these claims have no limitation with respect to the (S) conformation of the 2-(2,2-dimethylcyclopropanecarboxamido) group, and because Merck

---

[1] Merck's arguments concerning the alleged "invention" of Primaxin (Br. 1-2) and Ranbaxy's intention to sell a combination product containing cilastatin and imipenem (Br. 5) are not relevant to any issue of claim construction.

[2] Citations to "Br." are to Merck's Opening Claim Construction Brief (D.I. 38) filed on December 11, 2007.

states that cilastatin contains a 2,2-dimethylcyclo*propyl* group, not a 2-2 cyclo*propane* group. (Br. 3). Merck elsewhere admits that the "2,2-dimethylcyclopropyl" group in Claims 2 and 9 includes a chiral carbon, and that the chiral carbon could be in the (S) configuration or in the (R) configuration. (Br. 28). Merck does not deny that the claims encompass these stereo forms, and mixtures thereof. The same admission applies to the "2,2-dimethylcyclopropane" group in Claim 19. (Br. 17 n.6).

Merck further misstates Ranbaxy's position with respect to the "2,2-dimethylcyclopropyl" group in Claims 2 and 9. (Br. 28). Ranbaxy does not propose "that the Court construe claim 19 with respect of its use with [*sic*] the same chemical group, referred to as '2,2-Dimethylcyclopropane' in that claim." (Br. 28). Ranbaxy has not suggested, much less "proposed" that the different terms "dimethylcyclo*propyl*" and "dimethylcyclo*propane*" refer to the same chemical group, and neither Merck nor Ranbaxy seeks a claim construction that would redefine or conflate either of these common terms. In fact, Merck maintains that these terms require no construction. (Joint Cl. Const. Chart 12; Br. 9, 28).

Merck has proposed that the term "alkyl" means "a paraffinic hydrocarbon group which may be derived from an alkane by dropping one hydrogen from the formula." (Joint Cl. Const. Ch. 8; Br. 24; A1002). Ranbaxy agrees that this construction of "alkyl" and "alkane" is correct, and requests that the Court expressly adopt this joint construction, in order to forestall the possibility that Merck may later allege that there is no difference between the structurally different chemical entities "dimethylcyclopropyl" and "dimethylcyclopropane" as used in the claims of the '868 patent, and specifically in claims 2 and 9 on the one hand vs. claim 19 on the other. This art-recognized difference is described in Morrison & Boyd, *Organic Chemistry* (3rd ed. 1959), at 283, A2749), where a cyclopropane group is a three-carbon alkane ring with six hydrogen atoms, and a cyclopropyl alkyl group is derived from cyclopropane by removing a hydrogen atom. (*Id.* at 81-82, A2742-2743), illustrated with reference to "propane" and "propyl"

groups.).

With respect to the construction of "X" and "Y" in Claim 1, Merck states that "Ranbaxy never identified what issues it believes its proposed constructions are relevant to." (Br. 26). Lest Merck attempt to elaborate on this incorrect position at the hearing, Ranbaxy includes in the appendix its interrogatory responses specifying its position with respect to the lack of written description support for these terms (A2762-2799). Ranbaxy specifically informed Merck as follows:

> Claims 1, 22, 23 and 24 are each invalid under 35 U.S.C. §112, first paragraph, because the specification of the '868 patent does not provide a written description of a compound of the structural formula in which R2 is X, and X is unsubstituted or substituted branched or linear alkyl of three to ten carbon atoms wherein the substituents include cycloalkyl of three to six carbon atoms with the proviso that when said alkyl is substituted by said cycloalkyl, X is not more than ten total carbon atoms. (Response No. 4, pp. 18-19, A2779-2780).
>
> . . .
>
> Claims 1, 23 and 24 are each invalid under 35 U.S.C. §112, first paragraph, because the specification of the '868 patent does not provide a written description of a compound of the structural formula in which R^2 is Y and Y is cycloalkyl of three to six carbon atoms, unsubstituted or substituted with one or two substituents where said substituents are selected from the group consisting of halogen or alkyl of one to four carbon atoms. (Response No. 4, p. 19, A2780).

Ranbaxy provided similarly detailed explanations of its other invalidity defenses under 35 U.S.C. §112. (Response No. 4, pp. 18-20, A2779-2781). During the initial claim construction conference on November 26, 2007, Ranbaxy directed Merck's attention to the interrogatory responses, and informed Merck that they provide the basis for the proposed claim construction.

II. The term "a compound" (Claims 1 and 9)

Merck misapprehends Ranbaxy's position with respect to "a compound" in Claims 1 and 9, which is simply that this term should be construed to exclude a combination product

containing both "a compound" as claimed and a thienamycin-type antibiotic compound. Ranbaxy does not maintain that a corporation cannot elect to file separate patent applications directed to "a compound," and to the combination of that compound with other compounds. (*cf.* Merck Br. 14-16).

Ranbaxy's claim construction is based on the express, unmistakable, and unequivocal disclaimer of any scope of the present claims reciting "a compound" that could encompass such a combination product ('868 patent, 8:43-50). The cases cited by Merck (Br. 10-16) stand for the unremarkable proposition that a claim reciting "a" product ordinarily encompasses the product alone or in combination with other products. Those cases, however, do not deal with the facts at bar, namely, where the specification disclaims a specific use of the claimed compound in combination with another class of compounds, and where the patentee has elected to claim that combination in another patent – now expired. Merck's position improperly tries to extend the monopoly on its expired '208 patent.

Thus, Merck's general guidelines do not apply when, as here, the patent specification expressly disclaims a specific combination; the patentee separately claims the combination in a different line of patents; and the public relies for decades on this express disclaiming language by the patentee. When the patentee expressly states in the specification what the claimed invention is *not*, that admission binds the patentee in subsequent claim construction. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (the specification may reveal an intentional disclaimer or disavowal of claim scope by the inventor, and the inventor's intention, expressed in the specification, is regarded as dispositive); *MBO Labs., Inc. v. Becton, Dickson & Co.*, 474 F.3d 1323, 1330 (Fed. Cir. 2007) ("Prosecution arguments like this one which draw distinctions between the patented invention and the prior art are useful for determining whether

the patentee intended to surrender territory, since they indicate in the inventor's own words what the invention is not."); *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1319 (Fed. Cir. 2006) ("[w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question."); *quoting SciMed Life Sys. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001).

Merck essentially ignores these and other dispositive cases.

The circumstance that the '868 patent specification discloses both the claimed dipeptidase inhibitor compounds and thienamycin-type compounds (Merck Br. 12, 13-17) has nothing to do with the issue of whether the '868 patent disclaimed the combination. *See ACCO Brands, Inc. v. Micro Security Devices, Inc.,* 346 F.3d 1075, 1079 (Fed. Cir. 2003) (an alternative embodiment disclosed in the specification, but separately claimed in a divisional application, does not broaden the scope of claims that were subject to disclaimer). Merck was required to disclose the best mode of using "a compound" as claimed, even though it expressly disclaimed "a compound" when used in combination with thienamycin-type compounds. Clearly, Merck envisioned "a compound" as having utility, when used in combination with thienamycin-type compounds, since it separately patented the dipeptidase inhibitor-thienamycin compound combination in the now-expired '208 patent.

Merck now incorrectly states that "In fact, the '868 patent inventors advised the Patent Office and the public that the combination of dipeptidase inhibitors with thienamycin-type compounds was the invention of another. . . ." (Br. 13). In fact, Merck failed to inform the

examiners responsible for examining the series of applications leading to the '868 patent[3] of the existence of other copending applications containing claims directed to the combination products, and of the issued '208 patent claiming this combination. The sole reference to the combination applications in the '868 patent is a statement (8:45-50, A5) which identifies the first two applications in that series as "now abandoned," and refers to some other unidentified application "filed concurrently herewith."

Nothing in the '868 patent or its prosecution history indicates that the combination was "the invention of another." Merck now relies on the disclosure of the '208 patent (Br. 14), but neglects to mention that it never disclosed the existence of the '208 patent to the examiners responsible for examining the applications leading to the '868 patent. Although Merck has now admitted that the combination allegedly invented by Kahan and Kropp was made by a different inventive entity than "a compound" of the '868 patent (Br. 14), its arguments concerning inventorship (Br. 13-16) have nothing to do with the issue of claim construction, or the express disclaimer of the combination product in the '868 patent. The expiration of the '208 patent in 2002 (A2000) exhausted any legitimate claim to the combination product, and Merck must- now live with the consequences of its unequivocal disclaimer in the '868 patent.

III. The term "heptenoic acid" (Claim 19)

Remarkably, Merck's discussion of the scope of Claim 19, which strays far into extrinsic evidence (Br. 19-20), overlooks the precise intrinsic definition of the free acid to which dependent Claim 19 is expressly limited, when R^1 in independent Claim 9 is hydrogen ('868 5:11-19, A4) ("these compounds of formula I, when R^1 is H, are described and named as the free acids. . ."). Merck repeatedly ignores the fact that Claim 9 defines R^1 as H, an ester, ***or*** a

[3] Application Serial Nos. 05/927,212 (A36-37), 06/50,233 (A119), 06/465,577 (A363), 06/748,300 (A478), 06/878,391, 07/244,527, 07/641,317 and 07/839,725.

pharmaceutically acceptable cation, and that there is no overlap between these alternate definitions. Claim 19 recites "The *compound of claim 9* which is 7-(L-2-amino-2-carboxyethylthio)-2-(2,2-dimethylcyclopropanecarboxamido)-2-*heptenoic acid*." (emphasis added). To the extent that Claim 19 properly depends from Claim 9 (which is not conceded), R^1 in Claim 9 (to which Claim 19 refers) can *only* be H. According to the intrinsic definition, the compound of Claim 19 is therefore "described and named as the free acid." ('868 patent, 5:11-19, A4). This express recitation of "the compound of claim 9" which is a "heptenoic acid" necessarily excludes pharmaceutically acceptable salts, because R^1 cannot be both hydrogen and a pharmaceutically acceptable cation in dependent Claim 19. *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006).

Merck's assertion that the specification contains examples which refer to acid sodium salts, or acids in the form of salts (Br. 17-18), is beside the point. These ambiguous references cannot overcome the unequivocal language in parent claim 9, that R^1 is H *or* a cation. In a case on all fours, the specification of the patent at issue in *Pfizer. v. Ranbaxy* expressly described the most preferred embodiment of the invention as the atorvastatin "heptanoic acid, hemicalcium salt"[4] but this did not alter the construction of the claims required by the specific syntax, and the independent/dependent claim structure which are substantively identical to present Claims 9 and 19 of the '868 patent. 457 F.3d at 1291-1292.

Merck could have drafted Claim 19 to contain an alternate definition, *e.g.*, in which R^1 was *either* hydrogen or a pharmaceutically acceptable cation; instead, Merck limited Claim 19 to the free acid form, and nothing else. The express definition of R^1 in Claim 9, as either H *or* a

---

[4] U.S. Patent 5,273,995, 4:3-6 (A2754) ("The most preferred embodiment of the present invention is [R-(R*R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(l-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-*heptanoic acid, hemicalcium salt*.") (emphasis added).

pharmaceutically acceptable cation, excludes any possibility that dependent Claim 19, in which R^1 is H, could instead be a compound in which R^1 is not H.

This conclusion is compelled by *Pfizer v. Ranbaxy*, where the Federal Circuit relied on substantively identical claim syntax and dependent claim structure, in limiting the intermediate dependent claim to the free acid form, *i.e.*, excluding any "salt form" of the acid that was recited in the further dependent claim. 457 F.3d at 1292. Merck has not attempted to distinguish *Pfizer*. Although Merck refers generally to *Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367 (Fed. Cir. 2003) (Br. 17), in *Pfizer* the Federal Circuit distinguished *Teva* based on the specific claim syntax and dependent-independent claim relationship that is also present in the claims of the '868 patent. 457 F.3d at 1291 n. 6. Furthermore, the claim at issue in Teva was an independent claim, but present Claim 19 depends from Claim 9, and the acid recited in Claim 19 is necessarily limited to the free acid specified when R^1 is hydrogen in the independent claim. Thus, claim 20 which purports to broaden claim 19 by reciting a salt form of the acid, is clearly invalid under 35 U.S.C. §112, fourth paragraph.

As the Federal Circuit confirmed in *Pfizer*, it is simply immaterial that the specification or a person skilled in the art might refer to the "salt form" of an acid,[5] when the claim structure expressly excludes this possibility. 457 F.3d at 1292. The language of the claims, not the examples of the specification, delineate and limit the scope of the exclusive right.

With respect to Merck's assertion that the definition of R^1 in Claim 9 (and Claim 1 as well) does not require construction (Br. 21-22), it is clear that the term R^1 in this independent

[5] Like the '868 patent, the specification of the patent at issue in Pfizer expressly distinguished between the "free acid" of atorvastatin and "pharmaceutically acceptable salts" that are derived from the free acid. U.S. Patent 5,273,995, 2:57-65 (A2753). The specification further stated: "In practice, use of the *salt form* amounts to use of the *acid form* or *lactone form*." (emphases added) *Id.* 2:66-67 (A2753).

claim defines three mutually exclusive subgenera, according to the express language of the claims – using the term "or" to define permissible permutations. Indeed, the specification defines the compound as a free acid, when R^1 is H (5:11-19, A4). Throughout its brief, Merck simply ignores the unambiguous claim term "or" in defining the R^1 groups, which is fatal to its position. Claim construction is a question of law, and the proper construction of Claims 9, 19 and 20 of the '868 patent is controlled by the Federal Circuit's analysis of indistinguishable claim terminology and syntax in *Pfizer v. Ranbaxy*.

IV. The term "one to fifteen carbon alkyl" (Claim 1)

Merck asserts that Ranbaxy "cannot legitimately dispute that the word 'one' is a typographical error." (Br. 28). On the contrary, Merck cannot legitimately assert that the word "one" is a typographical error—"witho" (in Claim 22) may be a typographical error, but "one" clearly is not. There is a substantive error in Claim 1, which renders the claim indefinite under 35 U.S.C. §112, second paragraph, because R^3 cannot simultaneously be both "one to fifteen carbon alkyl" and "two to fifteen carbon alkyl."

It is not possible for the Court in the course of litigation to rewrite the claim by selecting one of the contradictory definitions ("two to fifteen carbon alkyl") that is *not* disclosed in the specification, and to cancel the definition ("one to fifteen carbon alkyl") that is the *only* definition provided in the specification.

Merck argues that this Court has the authority to bypass the Patent Office and rewrite a claim by correcting a substantive error that cannot be determined on the face of the patent, based on the assertion that the examiner failed to enter an amendment to the claim during prosecution. Merck's argument, and the "correction" which Merck seeks, are foreclosed by the Federal Circuit's decision in *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041 (Fed. Cir. 2001).

In that case, the Federal Circuit reiterated that a "district court can correct an error only if the error is evident from the face of the patent." 254 F.3d at 1302, *citing Novo Indus., L.P. v. Micro Molds Corp.,* 350 F.3d 1348, 1357 (Fed. Cir. 2003) and *Hoffer v. Microsoft Corp.*, 405 F.3d 1326 (Fed. Cir. 2005), the cases on which Merck relies. (Br. 29).

The claim at issue in *Group One* omitted language that should have been present, due to amendments made during prosecution, and the nature of the error and its correction were therefore both evident from the prosecution history. 407 F.3d at 1302. A printing error by the Patent Office resulted in the omission of this language. *Id.* at 1301 n.1. The error was not "evident on the face of the patent." *Id.* at 1303. Under these circumstances, the Federal Circuit instructed as follows:

> The prosecution history discloses that the missing language was required to be added by the examiner as a condition for issuance, but one cannot discern what language is missing simply by reading the patent. The district court does not have authority to correct the patent in such circumstances.

Id. at 1303. Merck's argument supporting correction of Claim 1 is that the prosecution history indicates that the examiner intended to amend the clause in dispute to recite "two to fifteen carbon alkyl" rather than "one to fifteen carbon alkyl." (Br. 30-31). Even if Merck's argument were accepted, *Group One* instructs that the Court does not have authority to correct the error in Claim 1, because the asserted error *and* its appropriate correction are not apparent on the face of the '868 patent.

It is plain enough that Claim 1 contains conflicting definitions of the R^3 alkyl group. However, from the face of the patent and the disclosure of the specification, it is manifestly unclear which of the conflicting clauses constitutes the "error" in the claim. Ranbaxy submits that it is apparent from the face of the patent that the recitation of "two to fifteen carbon alkyl" is in error, because the specification does not disclose this range, whereas it expressly describes R^3

as a "one to fifteen carbon alkyl group" as recited in Claim 1, *i.e.*, "wherein R^2 and R^3 are hydrocarbon radicals in the range respectively of 3-10 and 1-15 carbon atoms." ('868 patent, 1:60-61, A2). Nothing "from the face of the patent" suggests otherwise. There is certainly reasonable debate as to the correction that would be appropriate "from the face of the patent," which removes the proposed corrections from the ambit of the Court's authority. *Novo Indus., L.P. v. Micro Molds Corp.,* 350 F.3d 1348, 1357 (Fed. Cir. 2003). Claim 1 is clearly invalid for indefiniteness in its present form, as a matter of law. *See id.* at 1358.

As the Federal Circuit explained in *Group One*, "[b]ecause a reader of the patent in *Novo Industries* could not ascertain the error from the face of the patent, we held that it was beyond the district court's authority to guess at what was intended, and that the error, if any, could only be corrected by the PTO." 407 F.3d at 1303, *citing Novo Indus., L.P. v. Micro Molds Corp.,* 350 F.3d 1348, 1357-58 (Fed. Cir. 2003). In *Novo Industries*, as in the present case, it was apparent from the language of the claim itself that the claim contained errors because it recited "a rotatable with," which the patentee argued was an "obvious typographical error." 350 F.3d at 1353. Although the existence of some error was thus clear from the claim language itself, the appropriate correction was not apparent from the face of the patent.

Merck's argument that Claim 1 should be revised to eliminate the only disclosed definition, based on the theory that the claim recites "*said* one to fifteen carbon alkyl," similarly fails to state a basis on which the claim could be corrected. (Br. 29-30). *See Fuji Photo Film Co. v. ITC*, 386 F.3d 1095, 1101 (Fed. Cir. 2004) (the court will not correct "taking lens" to mean "taking lens means" even though a dependent claim refers to "said taking lens means" and there is a clear inconsistency in the claims, where it is not clear how this inconsistency should be resolved).

This answering brief on claim construction does not address in detail the lack of written description support required by 35 U.S.C. §112, first paragraph, for the two to fifteen carbon alkyl group in Claim 1, or the indefiniteness of Claim 1 under 35 U.S.C. §112, second paragraph. Ranbaxy submits that these issues involving the validity of Claims 1, 2, and 22-24 could be resolved by briefing prior to trial, if the Court should find this convenient.

V. The structural formula (Claims 1 and 9)

Merck does not address Ranbaxy's proposed construction of the general formula in Claims 1 and 9 (Br. 27), which specifies that the formula is generic, and encompasses all different isomeric compounds (*e.g.*, specific compounds within the scope of the formula having different three-dimensional configurations), and mixtures thereof. Indeed, Merck does not even acknowledge that this general formula includes various isomeric forms of compounds further defined by the substituents R^1, R^2 and R^3. Merck agrees that the "2,2-dimethylcyclopropyl" group in Claims 2 and 9 includes a chiral carbon, and that the chiral carbon could be in the (S) configuration or in the (R) configuration (Br. 28), yet refuses to agree to Ranbaxy's simple construction covering the stereo-forms of those compounds, and mixtures thereof.

This is Ranbaxy's basic point—that the general structural formula should be construed expressly to include each of the separate isomers of compounds described by the formula, and mixtures thereof, depending on the stereoconfiguration of chiral substituents that are selected. It is unclear why Merck seeks to dispute this point, but Ranbaxy seeks construction of the general formula to make sure that Merck does not later attempt to assert a narrower definition, in response to Ranbaxy's invalidity arguments.

VI. The term "pharmaceutically acceptable cation" (Claims 1 and 9)

Ranbaxy seeks a construction of "pharmaceutically acceptable cation" to make sure that Merck does not later attempt to narrow this term, in response to Ranbaxy's invalidity arguments.

Contrary to Merck's impression, Ranbaxy does not propose that "pharmaceutically acceptable cations" should include lethal poisons, such as radium salts. Ranbaxy proposes a construction that would encompass all pharmaceutically acceptable cations that are used to make pharmaceutical salt compounds, including, for example, any and all cations that are used to make pharmaceutical compounds listed in the F.D.A. Orange book or in the United States *Pharmacopeia*, or discussed in patents describing cations that are conventionally used to make pharmaceutical compositions.[6]

VII. The term "alkyl" (Claims 1 and 22)

Much of Ranbaxy's and Merck's opening briefs relate to the definition of elementary chemical terms such as "alkyl" when this term is used without further qualifying language to define substituents containing alkyl groups in R^3, and in X and Y of R^2. Ranbaxy seeks to avoid any later "shrink-wrap" interpretation by Merck that would confine the broadest ordinary meaning of the term "alkyl" to the meager description provided in the '868 patent. In the context of the specific claims at issue, if "alkyl" is not expressly qualified by a specific recited carbon number range, then it is appropriate for the term to be construed to encompass any linear,

---

[6] For example, U.S. Patent 5,273,995 (the patent at issue in *Pfizer v. Ranbaxy*, 457 F.3d 1284, 1292) describes "appropriate pharmaceutically acceptable salts" as follows:

> Appropriate pharmaceutically acceptable salts within the scope of the invention are those derived from bases such as sodium hydroxide, potassium hydroxide, lithium hydroxide, calcium hydroxide, l-deoxy-2-(methylamino)-D-glucitol, magnesium hydroxide, zinc hydroxide, aluminum hydroxide, ferrous or ferric hydroxide, ammonium hydroxide or organic amines such as N-methylglucamine, choline, arginine and the like. Preferably, the lithium, calcium, magnesium, aluminum and ferrous or ferric salts are prepared from the sodium or potassium salt by adding the appropriate reagent to a solution of the sodium or potassium salt, i.e., addition of calcium chloride to a solution of the sodium or potassium salt of the compound of the formula I will give the calcium salt thereof. (2:66-3:14, A2753).

branched or alkyl group, without reading any other specific limitation into the plain language of the claim. *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1118 (Fed. Cir. 2004) (in the absence of modifiers, general descriptive terms are typically construed as having their full meaning.)

With respect to R^3, the claim recites that R^3 includes either a 1-15 carbon alkyl or a 2-15 carbon alkyl, and states that the terminal carbon of this alkyl can be further substituted by various groups containing additional "alkyl" groups.[7] Nothing in the language of the claim, or in the specification of the patent, further defines or limits the number of carbon atoms or the structure of the substituent alkyl groups, for the simple reason that that the R^3 substituents at issue are not described in the specification as required by 35 U.S.C. §112, first paragraph. Ranbaxy accordingly seeks a construction that is consistent with the intrinsic evidence, *i.e.*, with the use of this term in the context of the patent claims, that would encompass, for example, at least all alkyl groups having 1-15 carbons atoms, that may be linear, branched, or cyclic. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (the claims themselves provide substantial guidance as to the meaning of particular claim terms, in context of surrounding words of the claim).

Without belaboring this point further, it is sufficient to point out that a standard reference work identifies common alkanes having up to 20 carbon atoms, and their various isomers, including straight chain, branched chain, and cyclic forms. (Morrison & Boyd, *Organic Chemistry* (3rd ed. 1959), at 80-82 (A2741) and 283-285 (A2749-2751)). Ranbaxy is entitled to a construction of "alkyl" that encompasses the full scope of this art-recognized term.

---

[7] The terms which require construction of "alkyl" in R^3 substituents are "tri*alkyl*ammonium," "quaternary hydroxy*alkyl*di*alkyl*ammonium," "phosphonyl*alkyl*amino," "hydroxy*alkyl*amino," "*alkyl*amidino," "N,N-di*alkyl*guanidino," "*alkyl*carbonyloxy," and "*alk*oxycarbonyl."

With respect to Ranbaxy's proposed construction of the specific alkyl groups encompassed by the definitions of X and Y in Claim 1, and R^2 in Claim 22, Merck does not contend that these terms have any narrower definition than that proposed by Ranbaxy. (Br. 24-27).

Because Merck refused to agree to the clear minimum scope of the term "alkyl," Ranbaxy was required to present this claim construction issue to the Court. Ranbaxy legitimately seeks to preclude Merck from later attempting to propose some narrower definition of the disputed terms, without identifying such a construction at the present stage of the litigation. Because Merck has failed to propose any other narrowing definition of the term "alkyl" in the disputed R^3 substituents, and in the definition of R^2, Ranbaxy's construction, which is based on intrinsic evidence,[8] should be adopted.

OF COUNSEL:
Mark Boland
Kenneth Burchfiel
Michael Dzwonczyk
Chid Iyer
Renita Rathinam
Sughrue Mion PLLC
2100 Pennsylvania Ave., N.W.
Suite 800
Washington, D.C. 20037
(202) 293-7060

Dated: December 21, 2007

Kelly E. Farnan
Frederick L. Cottrell III (#2555)
Cottrell @rlf.com
Kelly E. Farnan (#4395)
Farnan@rlf.com
Richards, Layton & Finger
One Rodney Square
920 N. King Street
Wilmington, DE 19899
(302) 651-7700
Attorneys for Defendant/Counterclaimant Ranbaxy Laboratories Limited and Ranbaxy Inc.

[8] Merck again relies on extrinsic evidence, rather than the intrinsic language of Claim 1. (Br. 23-24).

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 21, 2007, I electronically filed the foregoing document with the Clerk of Court using CM/ECF and caused the same to be served on the defendant at the addresses and in the manner indicated below:

HAND DELIVERY:

Mary B. Graham
James W. Parrett, Jr.
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
Wilmington, DE 19899

I hereby certify that on December 21, 2007, the foregoing document was sent to the following non-registered participants in the manner indicated:

FEDERAL EXPRESS:

Raymond N. Nimrod
Jenner & Block LLP
919 N. Third Avenue
37th Floor
New York, NY 10022-3908

Aaron A. Barlow
Gregory D. Bonifield
Jenner & Block LLP
330 N. Wabash Avenue
Chicago, IL 60611-7603

Kelly E. Farnan (#4395)